

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Kazuhiro ONO et al.

Conf. No. 3742

Group Art Unit : 1614

Appl. No. : 10/535,336

(U.S. National Phase of PCT/JP2003/014709)

I.A. Filed : November 19, 2003

Examiner : Lezah ROBERTS

For : AGENT FOR DISSOLVING DENTAL CALCULI AND DENTAL
CARIES

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AF
Randolph Building
401 Dulany Street
Alexandria VA 22314

Sir :

I, the undersigned, Kazuhiro ONO, a citizen of Japan, do solemnly declare as follows:

1. That I graduated from Kitasato University in Japan and received a MS degree in 1979 from said university. I also received a PhD degree from the Showa University in Japan in 1997. I have specialized in the field of chemistry and have engaged in research in the chemical field for approximately ten years. I have been an employee of Showa Yakuhin Kako Co., Ltd. since 1979 and am currently employed by said company in the Research and Development Division.
2. That I am one of the inventors of the above-referenced application.
3. That I have reviewed the Office Action mailed July 9, 2007 and the application as filed.

4. That experiments have been conducted under my direction to show reduction of weight of dental calculus using *Perilla frutescens* var. *crispa* polyphenols alone, glycolic acid alone, and a combination thereof, including Examples 3 and 18 in International Application No. PCT/JP03/14709 of which the above-identified application is the U.S. national stage.

5. That the experiments were performed, as follows:

Example 3

Dental calculus in an amount of 0.6 mg obtained by washing dental calculus collected from the oral cavity and then wiping water with KIMWIPES was immersed in 1 ml of an aqueous solution of *Perilla frutescens* var. *crispa* polyphenols (produced by Meiji Seika Kaisha, Ltd., prepared as a 5% aqueous solution) for 105 minutes. After the treatment, the dental calculus was washed with water, wiped with KIMWIPES and weighed. The weight was 0.3 mg, and thus remarkable reduction of the weight of dental calculus was observed.

Example 18

Dental calculus in an amount of 0.9 mg obtained by washing dental calculus collected from the oral cavity and then wiping water with KIMWIPES was immersed in 1 ml of a 10% aqueous solution of glycolic acid for 9 minutes. After the treatment, the dental calculus was washed with water, wiped with KIMWIPES and weighed. The weight was 0.5 mg, and thus remarkable reduction of the weight of dental calculus was observed.

Example Using Combination Of Glycolic Acid And Polyphenols

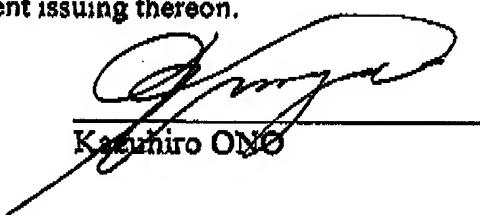
Dental calculus in an amount of 1.2 mg obtained by washing dental calculus collected from the oral cavity and then wiping water with KIMWIPES was immersed in 1 ml of an aqueous solution containing glycolic acid (10%) and *Perilla frutescens* var. *crispa* polyphenols (produced by Meiji Seika Kaisha, Ltd. Prepared as a 5% aqueous solution) for 6 minutes. After

The weight was 0.6 mg, and thus remarkable reduction of the weight of dental calculus was observed.

7. That in Example 3 wherein *Perilla frutescens var. crispa* polyphenol was used in the absence of inclusion of additional active ingredient, 50% weight of the dental calculus was dissolved after 105 minutes; that in Example 18 wherein glycolic acid was used in the absence of inclusion of additional active ingredient, 44% weight of the dental calculus was dissolved after 9 minutes; and that, in contrast, when polyphenol and glycolic acid are utilized in combination, there is obtained a more rapid dissolving of the dental calculus, i.e., 50% weight of the dental calculus was dissolved after 6 minutes.

8. The undersigned further declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-captioned application or any patent issuing thereon.

January 8, 2008
Date


Kazuhiro Ono